REMARKS

Claims 1 and 3-5 are pending in the instant application. Claims 4 and 5 have been canceled. Claims 1 and 3 have been rejected. Claim 1 has been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Rejection of Claims Under 35 U.S.C. §112

The rejection of claim 1 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention has been maintained. The examiner suggests that the specification does not reasonably provide a written description of "recombinant Fel dI wherein the baculovirus expressed recombinant Fel dI comprises chain 1 and chain 2" because recombinant Fel dI comprises chain 1 and chain 2 without SEQ ID NO have no structure much less function. Further, the Examiner has indicated that SEQ ID NO:5 is an oligonucleotide of glycine/serine linker whereas

the compound recited in claim 1 is a polypeptide. Applicants respectfully traverse this rejection.

In an effort to advance the prosecution of this application, Applicants have amended claim 1 to recite the oligonucleotide sequences which flank chain 1 and chain 2 and their corresponding SEQ ID NO. Support for this amendment can be found on page 4, lines 7-20. Oligonucleotides are highly sequence specific at an optimal annealing temperature and provide a defining structure for the intervening nucleic acid sequences of Fel dI chain 1 and chain 2. Using the combination of 5' and 3' sequences flanking chain 1 or chain 2, it would be well within the means of the skilled artisan to obtain the desired chain 1 and chain 2 nucleic acid sequences using the teachings of the instant application. Applicants have further amended claim 1 to indicate that the glycine/serine linker is encoded by the nucleic acid sequence of SEQ ID NO:5. Withdrawal of this rejection is therefore respectfully requested.

II. Rejection of Claims Under 35 U.S.C. §103

Claim 1 has been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,547,669 in view of U.S. Patent No. 5,395,750. Claim 3 has been rejected as being

unpatentable over U.S. Patent No. 5,547,669 in view of U.S. Patent No. 5,395,750 as applied to claim 1 and further in view of U.S. Patent No. 5,837,243. Claim 1 has been further rejected as being unpatentable over U.S. Patent No. 5,547,669 in view of U.S. Patent No. 5,395,750 and Bei et al. (1995) *J. Immunological Methods* 186:245-255).

U.S. Patent No. 5,547,669 teaches Fel dI chain 1, Fel dI chain 2 and Fel dI chains 1 and 2 linked together via a linker such as any non-epitope amino acid sequence or other appropriate linking or joining agent. The Examiner suggests that the claimed invention as recited in claim 1 differs from the reference in that the linker is a glycine/serine linker of SEQ ID NO:5.

U.S. Patent 5,395,750 teaches a method of making a compound such as a synthetic single chain antibody sequence such as heavy and light region sequences of any antibody is linked by a glycine/serine linker such as the claimed linker sequence of SEQ ID NO:5.

U.S. Patent No. 5,837,243 teaches bispecific molecules such as cat allergen linked to humanized or single chain (sFv) antibody H22 that binds to CD64. This reference also teaches

fusion molecules linked together via a linker such as glycine and serine.

Bei et al. teach that the baculovirus system may be used to produce the single-chain antibody CC49 which reacts with pancarcinoma antigen, tumor associated glycoprotein, and TAG-72. This reference further teaches a construct with sFv CC49 covalently joined to Fc(γ1) through a hinge and a construct having human IL-2 attached to the C-terminus of SCIg.

The Examiner suggests that it would have been obvious to one of ordinary skill in the art at the time that the invention was made to link Fel dI chain 1 and chain 2 in series as taught by U.S. Patent No. 5,547,669 using a linker such as glycine and serine as taught by U.S. Patent No. 5,395,750 and further have high levels of production in a baculovirus system as taught by Bei et al. The Examiner further suggests that it would have been obvious to one of ordinary skill to link the single chain humanized antibody H22 of U.S. Patent No. 5,837,243 to Fel dI chain 1 and chain 2 in series as taught by U.S. Patent No. 5,547,669 using a linker such as glycine and serine as taught by U.S. Patent No. 5,395,750. The Examiner further suggests that one having ordinary skill would have been motivated to do this

because U.S. Patent No. 5,547,669 teaches recombinant Fel dI is useful for treating and diagnosing sensitivity in an individual to cat allergen such as Fel dI, U.S. Patent No. 5,395,750 teaches a flexible glycine-serine linker, and U.S. Patent No. 5,837,243 teaches the antibody H22 is useful for targeting any antigen to the antigen presenting cell to a surface receptor such as CD64 on the antigen presenting cell thereby inducing tolerance to any antigen such as an allergen. Applicants respectfully traverse this rejection.

MPEP § 2143 states that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination must both be found in the prior art, and not based on the applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The novelty and unexpected feature of this invention is that baculovirus-produced, recombinant Fel dI protein has dramatically improved immunoreactivity for IgG and IgE antibody. Therefore, Applicants have further amended claim 1 to recite that the recombinant Fel dI protein of the invention binds human IgE and IgG at a level comparable to that of natural Fel dI. Support for this amendment can be found on page 3, lines 5-10 wherein recombinant Fel dI protein with or without a sFv of monoclonal antibody H22 bind human IgE at levels identical to natural Fel dI. While U.S. Patent No. 5,547,669 teaches Fel dI chains 1 and 2 linked together via a linker such as any non-epitope amino acid sequence or other appropriate linking or joining agent, this reference does not teach that a recombinant Fel dI protein containing chains 1 and 2 joined by a linker binds human IgE and IgG antibody at a level comparable to that of natural Fel dI. In fact, the experimental results provided in Figure 14 and column 23, lines 58-66 of U.S. Patent No. 5,547,669 indicate that the recombinant Fel dI proteins bound *significantly less* human IgE antibody than natural Fel dI protein. Further, this reference teaches away from the claimed invention as it demonstrates that a linker placed between chains 1 and 2 of Fel dI *decreases* IgE

binding compared to recombinant Fel dI chain 1 or recombinant Fel dI chain 2 alone. See Figure 14 of U.S. Patent No. 5,547,669. Thus, one of skill in the art would not be motivated to pursue linkers between chains 1 and 2 of Fel dI as a linker would have been expected to decrease IgE binding to recombinant Fel dI.

The secondary references of U.S. Patent No. 5,395,750 and U.S. Patent No. 5,837,243 fail to overcome the deficiencies in the teachings of this primary reference as they do not indicate that a baculovirus-produced recombinant Fel dI protein has activity comparable to natural Fel dI protein. While Bei et al. teach that the specificity and binding of the baculovirus produced antibodies were comparable to those derived from mammalian cells, in light of the decreased binding of recombinant Fel dI proteins taught by U.S. Patent No. 5,547,669, one of skill in the art would not be motivated to combine the teachings of Bei et al. with U.S. Patent No. 5,547,669 to arrive at the claimed invention. Thus, withdrawal of this rejection is respectfully requested.

III. Conclusion

The Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

Jane Massey Licata
Registration No. 32,257

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Licata & Tyrrell P.C.
66 E. Main Street
Marlton, New Jersey 08053

(856) 810-1515